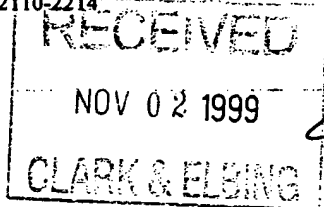


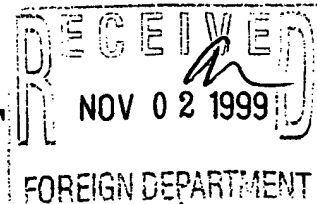
PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: KAREN L. ELBING
CLARK & ELBING, LLP.
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BOSTON, MA 02110-2214



PCT



WRITTEN OPINION

DOCKETED FOR
ATTORNEY
UMX

PCT Rule 66)

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APR 08 2002
TECH CENTER 1600/2900

Date of Mailing
(day/month/year)

28 OCT 1999

Applicant's or agent's file reference
00786/361WO2

REPLY DUE

within TWO months
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International application No.

PCT/US98/25247

International filing date (day/month/year)

25 NOVEMBER 1998

Priority date (day/month/year)

25 NOVEMBER 1997

International Patent Classification (IPC) or both national classification and IPC
IPC(6): C12Q 1/00, 1/02 and US Cl.: 435/4, 7.32

Applicant

THE GENERAL HOSPITAL CORPORATION

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 25 MARCH 2000

Name and mailing address of the IPEA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

BRENDA BRUMBACK CV

Telephone No. (703) 308-0196

WRITTEN OPINION

International application No.

PCT/US98/25247

I. Basis of the opinion

1. This opinion has been drawn on the basis of (Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".):

- ☐ the international application as originally filed.
- ☒ the description, pages 1-73, as originally filed.
 pages NONE, filed with the demand.
 pages NONE, filed with the letter of _____
- ☒ the claims, Nos. 1-43, as originally filed.
 Nos. NONE, as amended under Article 19.
 Nos. NONE, filed with the demand.
 Nos. NONE, filed with the letter of _____
- ☒ the drawings, sheets/fig NONE, as originally filed.
 sheets/fig 1-160, filed with the demand.
 sheets/fig NONE, filed with the letter of _____

2. The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/fig NONE

3. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box Additional observations below (Rule 70.2(c)).

4. Additional observations, if necessary:

NONE

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V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>1-37</u>	YES
	Claims <u>38, 39, 41 and 43</u>	NO
Inventive Step (IS)	Claims <u>1-37</u>	YES
	Claims <u>38-43</u>	NO
Industrial Applicability (IA)	Claims <u>1-43</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-37 meet the criteria set out in PCT Article 33(2)-(4) because the prior art does not teach or fairly suggest nucleic acid molecules of SEQ ID NOs: 252, 105, or 106; or polypeptides of SEQ ID NOs: 253, 107, or 108; and does not teach or fairly suggest methods of using the nucleic acid molecules or polypeptides to identify compounds capable of decreasing expression of a pathogenic virulence factor or compounds capable of binding the polypeptides.

Claims 38, 39, 41, and 43 lack novelty under PCT Article 33(2) as being anticipated by Molanari et al. Molanari et al teach methods of identifying compounds which inhibit the virulence of *Pseudomonas aeruginosa*, as measured by detecting the presence of pyocyanin in culture.

Claims 40 and 42 lack an inventive step under PCT Article 33(3) as being obvious over Molanari et al in view of Cohn et al. Molanari et al teach detection of pyocyanin as a measure of *P. aeruginosa* virulence. Molanari et al teach detection of the pyocyanin visually. Cohn et al teach detection of pyocyanin spectroscopically at an absorbance of 520nm. Because Molanari teach detection of pyocyanin as a measure of *P. aeruginosa* virulence and Cohn et al teach detection spectroscopically, the claimed invention cannot be considered as having required an inventive step.

NEW CITATIONS

Database Medline on Dialog, No. 01659441, COHN et al, "The effect of amiloride on pigment expression in a clinical isolate of *Pseudomonas aeruginosa*." Current Therapeutic Research - Clinical and Experimental, Abstract, April 1992, Vol. 51, No. 4, pp. 562-567.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

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